Missouri Guidelines for the Use of Controlled Substances for the Treatment of Pain

Effective January 2007, the Board of Healing Arts appointed a Task Force to review the current statutes, rules and guidelines regarding the treatment of pain. This Task Force consisted of both staff and Board members, with input from the Governor's Council on Pain and Symptom Management. They were charged with gathering information and to draft language for the Board to review.

In the report, the committee members made recommendations that included:

- ✓ Developing a pain and symptom management website for healthcare professionals and the general public.
- ✓ Encouraging hospitals to increase their medical and nursing staff's knowledge by providing guidelines for required curricula in pain and symptom management in their educational programs.
- ✓ Encouraging pharmacies within communities or among pharmacy chains to share information and stock adequate supplies of Schedule II medications to meet the needs of patients.
- ✓ Evaluating patients with complete history and physicals and adding previous pain physician(s) records with their current medical records.
- ✓ Documenting any pain agreements between the patients and the physician and add this along with an informed consent to the medical records.
- ✓ Making appropriate referrals.

The Missouri Guidelines are not intended to define complete or best practice but rather to communicate what the Board considers to be within the boundaries of professional practice. The guidelines state that patients should have access to appropriate and effective pain relief that will serve to improve the quality of life for those who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain.

The Missouri guidelines have been broken down into the following sections:

- Section I: Preamble
- Section II: Guidelines (Evaluation of the Patient: Treatment Plan; Informed Consent and Agreement for Treatment; Periodic Review; Consultation; Medical Records; Compliance with Controlled Substances Laws and Regulations)
- Section III: Definitions (Acute Pain; Addiction; Analgesic Tolerance; Chronic Pain; Pain; Physical Dependence; Pseudoaddiction; Substance Abuse; Tolerance)

To view and/or print a complete copy of the Missouri guidelines, please go to our website at www.pr.mo.gov/healingarts.asp

The Missouri Guidelines for the Use of Controlled Substances for the Treatment of Pain

Section I: Preamble

The Missouri Board of Healing Arts recognizes that the people of the State of Missouri have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. The Board encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing controlled substances.

These guidelines have been developed to clarify the Boards' position on pain control, to alleviate physician uncertainty and to encourage better pain management.

The Board recognizes that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. Physicians are referred to the U.S. Food and Drug Administration Consumer Magazine the March/April 2004 Issue Publication number FDA04-1336C entitled "Managing Chronic Pain", for a sound approach to the management of chronic pain. The medical management of pain should be based on current knowledge and research and include the use of both pharmacologic and non-pharmacologic modalities. During the treatment of pain the quantity and frequency of doses should be adjusted according to the intensity and duration of the pain. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics are not synonymous with addiction.

The Board is obligated under the laws of the State of Missouri to protect the public health and safety. The Board recognizes that prescribing of controlled substances, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Physicians should be aware of the methods for preventing the diversion of drugs for illegitimate purposes.

Physicians should not fear disciplinary action from the Board or other state regulatory enforcement agencies for prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and based on sound clinical grounds. Sound clinical grounds include a working diagnosis for the etiology of the pain. The Board will consider prescribing, ordering, administering or dispensing controlled substances for pain to be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain or if based on sound clinical grounds. All such prescribing must be accompanied by clear documentation in

the medical record of the treatment and in compliance with applicable state or federal law with the Board of Healing Arts § 334 RSMo; §334.105 RSMo; and §195 RSMo and with the Bureau of Narcotic and Dangerous Drugs and the Drug Enforcement Agency §21 USC.

Each case of prescribing for pain will be evaluated on an individual basis. The Board will not take disciplinary action against a physician for failing to adhere strictly to the provisions of these guidelines, if good cause is shown for such deviation. The physician's conduct will be evaluated to a great extent by the treatment outcome, taking into account whether the drug used is medically and/or pharmacologically recognized to be appropriate for the diagnosis, the patient's individual needs—including any improvement in functioning—and recognizing that some types of pain cannot be completely relieved. The Board will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing. The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors. The following guidelines are not intended to define complete or best practice, but rather to communicate what the Board considers to be within boundaries of professional practice.

Section II: Guidelines

The Board has adopted the following guidelines when evaluating the use of controlled substances for pain control:

1. Evaluation of the Patient

A complete medical history and physical examination must be conducted and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of controlled substances.

2. Treatment Plan

The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

3. Informed Consent and Agreement for Treatment

The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is incompetent. The patient should receive prescriptions from one physician and one pharmacy where possible. If the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the physician should consider the use of a written agreement between physician and patient outlining patient responsibilities, including

- urine/serum medication levels screening when requested;
- number and frequency of all prescription refills; and
- reasons for which drug therapy may be discontinued (i.e., violation of agreement).

4. Periodic Review

At reasonable intervals based on the individual circumstances of the patient, the physician should review the course of treatment and any new information about the etiology of the pain. Continuation or modification of therapy should depend on the physician's evaluation of progress toward stated treatment objectives, such as improvement in patient's pain intensity and improved physical and/or psychosocial function, i.e., ability to work, need of health care resources, activities of daily living and quality of social life. If treatment goals are not being achieved, despite medication adjustments, the physician should reevaluate the appropriateness of continued treatment. The physician should monitor patient compliance in medication usage and related treatment plans.

5. Consultation

The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangement pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

6. Medical Records

The physician should keep accurate records including complete medical history and physical examination;

- diagnostic, therapeutic and laboratory results;
- evaluations and consultations;
- treatment objectives;
- discussion of risks and benefits;
- treatments;
- medications (including date, type, dosage and quantity prescribed);
- instructions and agreements; and
- periodic reviews.

Records should remain current and be maintained in an accessible manner and readily available for review.

7. Compliance With Controlled Substances Laws and Regulations

To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration and (any relevant documents issued by the state medical board) for specific rules governing controlled substances as well as applicable state regulations. The Physician's Manual can be found at the DEA Diversion website at www.deadiversion.usdoj.gov . The State guidelines can be found under Chapter 195.070 RSMo and 334.105 RSMo.

Section III: Definitions

For the purposes of these guidelines, the following terms are defined as follows:

Acute Pain
Acute pain is the normal, predicted physiological response to an adverse chemical, thermal or mechanical stimulus and is associated with surgery, trauma and acute illness. It is generally time-limited and is responsive to opioid therapy, among other therapies.

Addiction
Addiction is a neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm. Addiction may also be referred to by terms such as "drug dependence" and "psychological dependence." Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction.

Analgesic Tolerance
Analgesic tolerance is the need to increase the dose of opioid to achieve the same level of analgesia. Analgesic tolerance may or may not be evident during opioid treatment and does not equate with addiction.

Chronic Pain
A pain state which is persistent and in which the cause of the pain cannot be removed or otherwise treated. Chronic pain may be associated with a long-term incurable or intractable medical condition or disease.

Pain
An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Physical Dependence
Physical dependence on a controlled substance is a physiologic state of neuro-adaptation which is characterized by the emergence of a withdrawal syndrome if drug use is stopped or decreased abruptly, or if an antagonist is administered. Physical dependence is an expected result of opioid use. Physical dependence, by itself, does not equate with addiction.

Pseudoaddiction
Pattern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction.

Substance Abuse
Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

Tolerance
Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect, or a reduced effect is observed with a constant dose.